Developing self-sustainable models of care for non-communicable diseases in Kenya

by

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I want to dedicate my work to my family who have supported me throughout my career and have accommodated the many challenges that arise in developing the programs we have established in western Kenya.

Declaration: I, Dr Sonak PASTAKIA, declare this thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree. This work was carried out between Jun 2007 and Oct 2016.

I am the first or the last author for six of the eight publications. All the work presented was conceived, designed and carried out by the author with the help of other collaborators (co-authors). The data analysis and interpretation was carried out by the author. Detailed contributions by co-authors are outlined below:

Publication 1: I performed all the data analysis but received support from my collaborators in cleaning the data and obtaining the data regarding interventions. My collaborators also assisted with writing up the manuscript.

Publication 2: I led and performed the analyses for the project and received support from my collaborators in collecting and writing up the results.

Publication 3: I conceptualized, designed, analyzed, acquired grant funds and assisted in the write up of the paper. The first author, Imran Manji was responsible for the leadership of the initiative and also finalizing the paper. The other collaborators assisted with the write-up and implementation of the work.

Publication 4: I was in charge of all aspects of the study and received support from my collaborators in collecting the data for analysis, providing descriptive analysis, and writing up the results.

Publication 5: I was in charge of all aspects of the study. I received support from my collaborators in implementing the project, collecting the data, cleaning the data, and assisting in the writing of the paper.

Publication 6: I was the first author but collaboratively worked with the team to put forth our view on the best approaches to utilize regarding health system strengthening through training in LMICs.

Publication 7: I was a co-investigator responsible for acquiring the funds, providing supervision over the project, and assisting in the writing of the paper. My collaborators led the writing of this article and I provided support.

For publication 8 describing consideration for the delivery of diabetes care in rural areas, I was the PI for the work and received support from my collaborators in writing up our findings, performing the descriptive analysis.

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Abstract

Background (Kenya)

Sub-Saharan Africa (SSA) is in the midst of experiencing an unprecedented increase in non-communicable diseases (NCD), specifically diabetes and hypertension(1, 2). This shift has required public sector health systems, which have historically focused on managing acute diseases, to redesign their services to appropriately serve chronic disease needs(3).

Issue Addressed

In order to provide a description of our efforts to bring up comprehensive services for NCDs in rural Kenya within this thesis, I have specifically selected publications which target different aspects of the healthcare system. This includes our efforts related to clinical training for pharmacists, screening for NCDs, medication supply chains, remote phone-based care services, and care delivery based in the community. Prior to the implementation of the programs mentioned in these domains, access to these services was largely not available in western Kenya. Furthermore, the publication of our research from this western Kenyan cohort is designed to supplant the relatively limited research which emanates from rural sub-Saharan Africa (4).

Research Questions

For each of these selected publications, we defined a set of primary and, in some cases, secondary research questions focused on identifying the contextualized attributes of service delivery in this setting while also assessing the impact. For the first publication on training for clinical pharmacists, we assessed the impact of Kenyan Bachelor of Pharmacy interns and North American Doctor of Pharmacy interns while providing clinical care in an inpatient setting in Kenya. Our primary research question assessed whether there was a significant difference in the number of clinical interventions documented by interns from the two countries.

In the second paper, we shifted our focus to outpatient care and wanted to address the uptake of different strategies of screening for diabetes and

hypertension. Our primary research question assessed whether there were any significant differences in follow-up at the public sector clinic after screening positive via home-based screening (community health volunteer provides screening at your home) versus community-based screening (a community wide event is established where people voluntarily show up to receive screening) in a rural setting.

In the third paper, we sought to continue to improve aspects of outpatient care by describing our model for improving access to medications. Our primary research question focused on descriptively assessing the change in availability of essential medications before and after implementation of this model.

In the fourth paper, we described and assessed our model for providing intensive diabetes follow-up remotely. Our primary research question focused on whether patients experienced statistically significant improvements in blood glucose control after participating in this service for six months.

In the fifth paper, we brought together various elements of our prior activities to design and evaluate the community-based model of care called BIGPIC - Bridging Income Generation through grouP Integrated Care. The primary research question for this investigation was to identify the frequency with which patients who screened positive for diabetes or hypertension linked to care. Secondary research questions compared the linkage frequency observed with this model compared to a historical control, along with a descriptive assessment of the loss to follow up, and an assessment of whether this model led to statistically significant reductions in blood pressure after 1 year of implementation.

Short Summary of the Individual Papers with Results Linking Them Together

Within our assessment of pharmacy training, we found that the Kenyan pharmacy interns provided statistically significantly more clinical interventions per day than their North American counterparts. This result highlighted the potential for Kenyan pharmacy providers to provide clinical

services which were largely unavailable in western Kenya prior to this research. Despite the lack of the clinically focused Doctor of Pharmacy curriculum in Kenya, Kenyan pharmacy interns within the Bachelors in Pharmacy program were able to make an average of 16.7 consultations per day with the medical team compared to 12.0 per day for the North Americans.

In the second paper we shifted our focus to the outpatient setting and were surprised to find that there weren't any statistically significant differences in follow-up between home-based versus community-based screening for NCDs. This highlighted the reluctance of rural patients to travel to public sector facilities for care regardless of the screening method utilized. This realization led us to simultaneously focus on improving the reliability of services available in public sector while also trying to implement solutions to facilitate the provision of remote services for care. Within our efforts to improve medication access in paper 3, we were able to demonstrate how our revolving fund pharmacy model was able to improve access to medications from <40% to >90%. In paper 4, we were able to implement a self-monitored blood glucose program and demonstrate a dramatic improvement in the blood sugars of patients enrolled in the self-monitored blood glucose program with a statistically significant 31.6% absolute decline in HbA1c. The culmination of these efforts and learnings is described in paper 5, where we implemented the BIGPIC care delivery model which resulted in a statistically significant improvement in linkage to care for screened patients, a retention in care frequency of 70.3%, and a statistically significant mean decline in the systolic blood pressure of 21mmHg (95% CI 13.9-28.4, P<0.01).

Summary of findings from the relevant publications

Background

Sub-Saharan Africa (SSA) is in the midst of experiencing an unprecedented increase in non-communicable diseases (NCD) (1, 2). This shift has required public sector health systems, which have historically focused on managing acute diseases, to redesign their services to appropriately serve chronic disease needs (3). These challenges are even more pronounced for hard to reach rural populations which tend to be in greater need of support because of their lower socioeconomic status.(5)

Despite having more than 75% of populations in low- and middle- income countries (LMIC) living in rural areas, the primary concentration of healthcare resources is in urban areas with only limited investigation in rural areas (6). These dynamics have led to an environment where patients in rural areas have limited access to NCD services despite recent evidence suggesting a growing burden of non-communicable diseases, specifically diabetes and cardiovascular disease (1, 2).

With the focus of care and research in urban areas, many efforts to extend access have tried to force fit strategies for urban settings into dissimilar rural settings(7, 8). This approach has yielded suboptimal results as the barriers to rural care access require a re-thinking of healthcare delivery to build contextualized models designed around the challenges these populations face (5).

In response to these challenges, the Academic Model Providing Access to Healthcare (AMPATH) has been advancing comprehensive, contextualized care delivery in western Kenya. AMPATH, started in 1989, has created one of the largest HIV treatment programs with over 150,000 ever enrolled HIV patients(9, 10). In order to provide comprehensive care and expand beyond this initial focus on HIV care, AMPATH has brought together a consortium of North American Universities to provide interdisciplinary care. It is within this backdrop that the Purdue University College of Pharmacy (PUCOP), under my leadership, was invited to provide on the ground support to the AMPATH program as illustrated in Figure 1. This thesis will describe the various

implementation research initiatives undertaken by the team I work with at AMPATH between July 2007 and October 2016. The structure of the Purdue Kenya Partnership within the AMPATH program and the chronology of these efforts can be seen in Figures 1 and 2. For the purpose of this thesis, I have selected areas of implementation that have been built upon each other to assist in improving different aspects of care delivery for chronic diseases (primarily hypertension and diabetes) while also describing the evolution of my different research efforts. In Figure 2, the chronology of the initiatives described in this thesis can be seen. My early efforts, described in papers 1-4, all build upon each other and have provided the learnings we incorporated into our more comprehensive BIGPIC model. Figure 2 also describes the current status of the work related to each published paper in this thesis by listing various indicators which highlight different metrics which characterize the present scale of these initiatives (the scale up is not discussed within the thesis itself).

These areas of emphasis within the thesis include creation of **training** programs, assessment of **screening** strategies for chronic diseases (diabetes and hypertension), development of systems to enhance medication **availability**, implementation of **remote** care delivery strategies, and design of **integrated** care strategies.

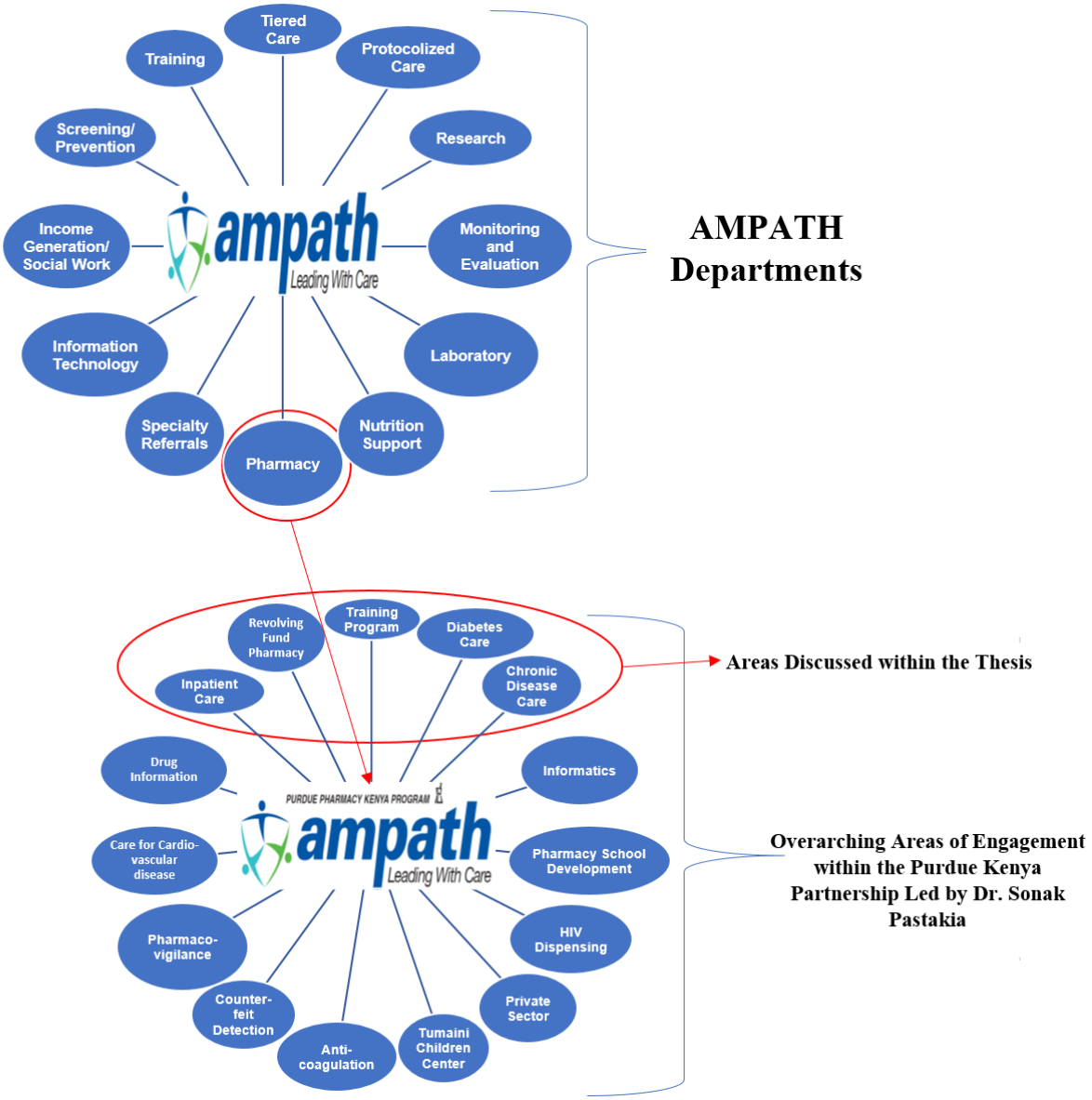
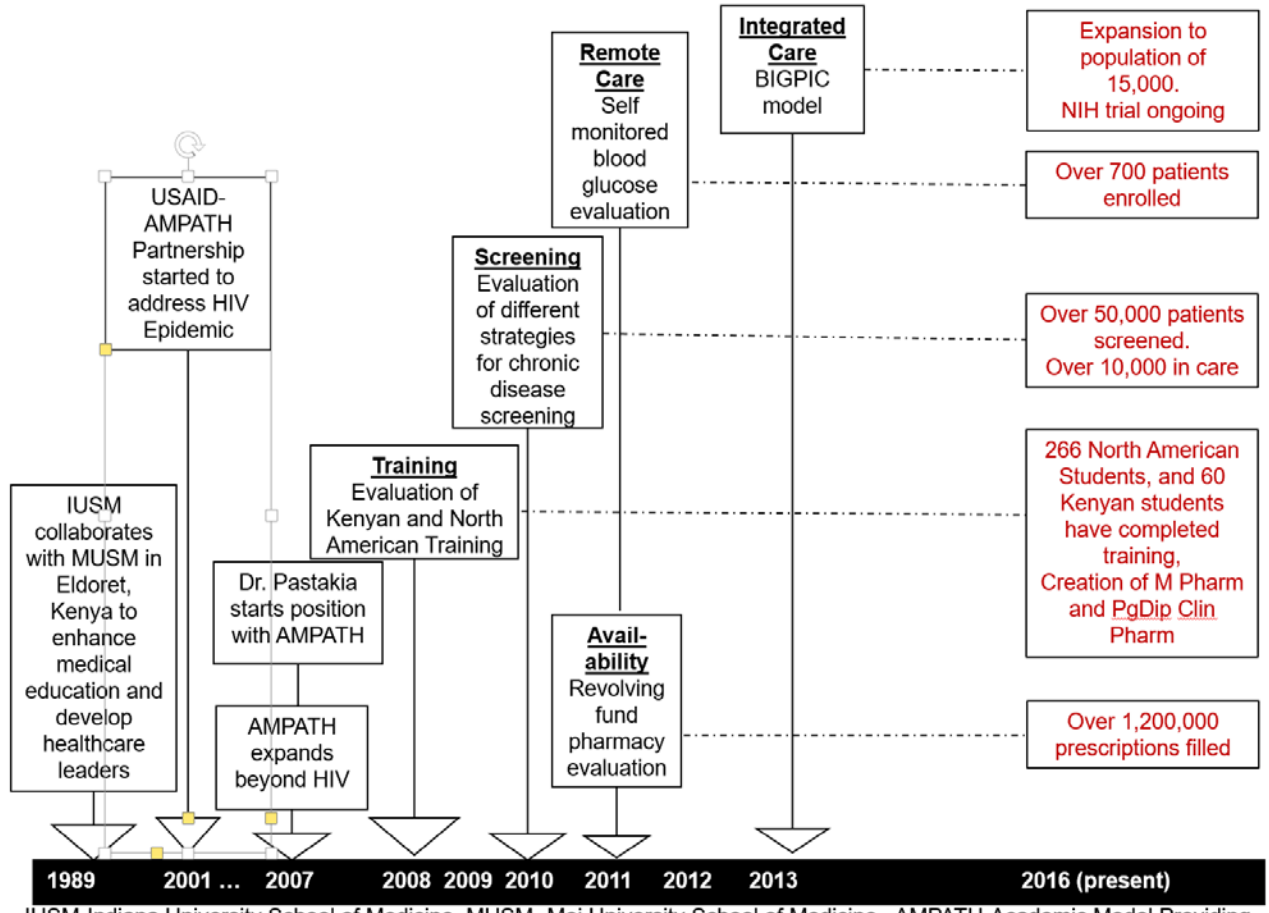


Figure 1 Structure of the Academic Model Providing Access to Healthcare and the Relationship to Materials Covered Within this Thesis



IUSM-Indiana University School of Medicine, MUSM- Moi University School of Medicine, AMPATH-Academic Model Providing Access to Healthcare M Pharm-Masters in Clinical Pharmacy, PgDip – Post graduate diploma in clinical pharmacy, red sections not discussed in thesis

Figure 2 Chronology of AMPATH and the Activities Described Within This Thesis

Training

There has been considerable emphasis on the relative lack of healthcare workers available in SSA and LMIC to respond to the growing needs of the population(11). The pharmacy workforce is a prime example of this deficiency as it has been shown that the lower the World Bank Income Status Classification of a country, the fewer pharmacists and pharmacies that are present to serve the population(12). As a region, SSA currently faces the greatest pharmacy workforce shortage in the world with the lowest pharmacist to population density which is as low as 5 per 100,000 in some countries(12).

While many efforts have successfully focused on increasing the numbers of healthcare workers, there is an equally important need to improve the quality and output of the currently available providers(13).

In order to maximize the clinical outcomes that can be achieved with these limited healthcare worker resources, it is vital that all members within the interdisciplinary healthcare team work together to appropriately task shift duties instead of requiring the few available physicians to independently provide the majority of clinical services.

These realizations led our team of Kenyan and North American pharmacists to propose that a new cadre of pharmacist in LMICs that can more effectively respond to both the clinical needs and medication supply needs of LMIC populations, could ultimately improve patient outcomes. Despite the availability of clinical pharmacy providers in high-income countries, this is largely a non-existent practice in Kenya and most of SSA where pharmacists typically only participate in the dispensing of product(14). We sought to assess the feasibility and impact of incorporating these providers within a rural inpatient setting in western Kenya, a rather typical setting for East Africa. Our primary research question was to determine whether North American Doctor of Pharmacy students and Kenyan Bachelors of Pharmacy students could provide similar numbers of interventions in inpatient care.

Diabetes Screening and Linkage Strategies

After our initial emphasis on training the staff needed to participate in an inter-disciplinary team, we sought to characterize different aspects of screening for NCD's to optimize our ability to get patients to participate in screening and subsequently attend facilities where care could be provided. While there has been considerable emphasis on researching the characteristics of NCD screening and treatment in urban centers in SSA, there has only been limited investigation on these dynamics in rural centers which tend to have their own unique barriers to care accession(7, 8). Within AMPATH's prior qualitative investigations of the various barriers to care linkage for hypertension in AMPATH's western Kenyan catchment area (see

Figure 3), our team of AMPATH researchers have found the primary barriers relate to the transportation difficulties in reaching remote facilities across rural terrain, financial challenges with affording the costs of care, and lack of trust in rural facilities (15). As seen in Figure 3, AMPATH covers a vast rural catchment area with numbered and labeled primary health centers facilities scattered across this area. This map highlights the transportation and subsequent financial challenges patients face in paying the costly expenses to reach remote facilities. The publications included within this thesis include activities conducted across western Kenya in Eldoret (Moi Teaching and Referral Hospital and Moi University), Webuye (Webuye SDH), Mosoriot (Mosoriot PRTC), Turbo (Turbo Health Centre), and Sinoko (near Sinoko Dispensary and Webuye SDH).

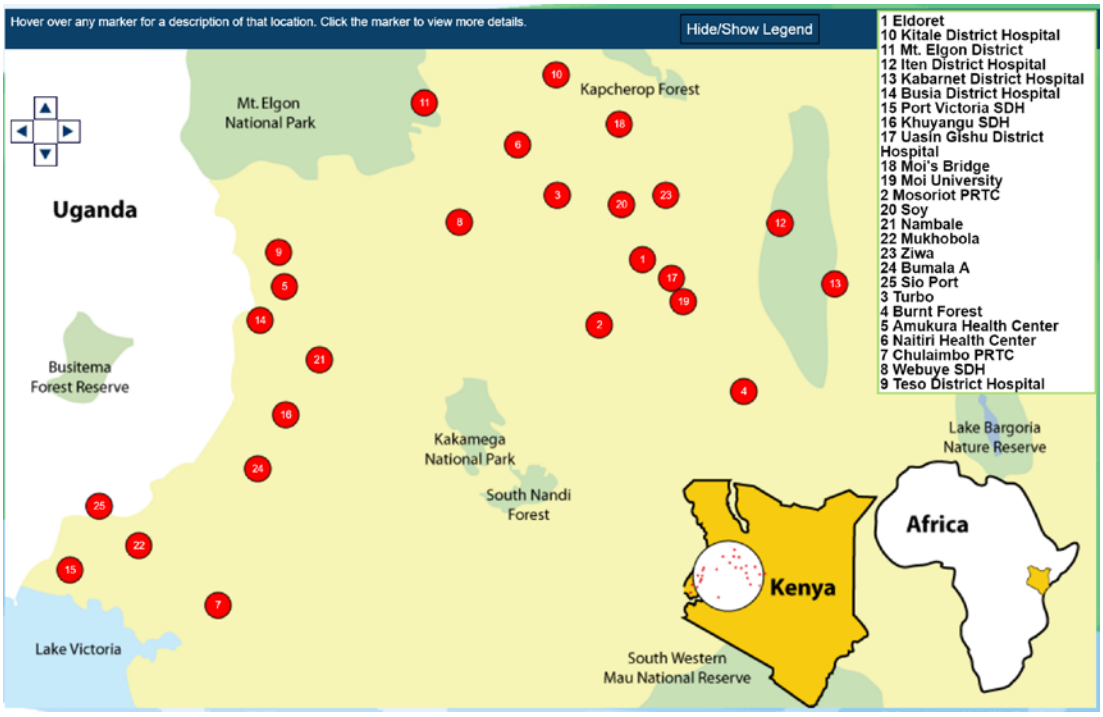


Figure 3 - Map of Main AMPATH Facilities Across Western Kenya(16)

In order to complement our qualitative analysis of barriers to linkage to care, we wanted to assess the quantitative linkage to care after utilizing different screening strategies for NCD's as there weren't any previous comparison studies looking at the differences in linkage when using home- versus community-based screening. Without an emphasis on studying actual patient behaviors related to linkage to care after screening, we knew the impact of

our costly screening efforts would be muted without a greater understanding of this crucial, understudied aspect of health care access. This set the stage for one of our first investigations where we assessed the prevalence and linkage frequencies of NCDs when using the home and community-based screening strategies.

Enhancement of Medication Availability within the Public Sector Supply Chain Systems

As we identified the main barriers to getting patients to access health care, the need for sustainable systems to meet the demands of the many patients now seeking access to care became very clear. With the availability of medications for non-communicable diseases in the public sector estimated at less than 36% across SSA, the many patients seeking care are often left without viable care options as they incur considerable extra expense traveling to poorly stocked facilities which are incapable of reliably addressing their basic health needs (17). This is further complicated by the many reports highlighting the high frequency of falsified and substandard medications in SSA(18). We postulated that this inadequately performing supply chain was one of the main culprits behind the low uptake of NCD services and resultant poor outcomes consistently reported throughout SSA for NCDs like diabetes(19). In order to counter this, we wanted to prove that it is possible to create a reliable and sustainable supply chain system incorporating quality assured medications at affordable prices for rural populations in partnership with the MOH. We also wanted to prove that much higher availabilities of medications could be achieved in these facilities which would result in greater uptake and utilization of pharmacy services.

Remote Care Delivery

As we addressed several of the healthcare system's needs in training pharmacy providers and ensuring access to potentially life-saving commodities, we began to develop a greater awareness of the many high risk patients in need of much closer medical supervision. These needs for

closer follow-up were especially pronounced for patients with insulin dependent diabetes. Unfortunately, most public sector SSA healthcare settings are not equipped to provide the recommended care strategies for chronic diseases like diabetes, as standard services such as having a basic point of care glucometers and glucose strips are only available at a median of 13% of public sector facilities in countries sampled across SSA. The poor availability of glucose monitoring supplies in facilities makes the prospect of home-based monitoring a distant consideration for the vast majority of patients in need of such services. While glucometers are available for purchase in the private sector, the vast majority of patients, especially those in rural areas, do not have them incorporated as a part of their care(20, 21). This is further complicated by the relatively lower literacy levels which highlight another challenge in implementing more intensive monitoring strategies which require considerable patient education and understanding to maximize the impact(22, 23).

We hypothesized that despite the relatively lower literacy reported for populations like those found in rural western Kenya, we could impart significant benefit from an intensive glucose monitoring program if the supplies and guidance were provided to participate in this modality of care.

Integrated Care Delivery Strategies

While our activities with the supply chain and more intensive management have improved the care patients who travel to facilities receive, it has not sufficiently improved the health outcomes of entire communities as desired as only a small percentage of patients end up seeking care. It is because of these realizations that we have arrived at the main focus of this thesis- the Bridging Income Generation through grouP Integrated Care (BIGPIC) program. Through our extensive experience in building up other components of the healthcare system related to training, screening, supply chain support, and phone based care delivery; we had a well-developed foundation of care delivery that we proposed could be used to extend cost-effective care delivery within the community. For example, through the scale-up of the

Revolving Fund Pharmacy model, medications were now readily available throughout public sector facilities within our catchment area. This reliable pharmacy infrastructure was then used to supply medications directly to community groups without requiring them to incur the costly expenses associated with traveling to facilities. By leveraging the foundational infrastructure we have built, we were able to create new models of care that are purposefully designed to provide sustainable, replicable, and cost-effective care in rural settings to overcome the aforementioned barriers. Our primary questions with our initial research efforts on this novel model were the following:

1. Do linkage and retention rates to care for patients who are screen positive for NCDs change when you shift to this more comprehensive holistic approach?
2. What kind of clinical outcomes are observed when the full complement of services and medications for NCD care are provided in a portable, microfinance group linked delivery model

For our pilot evaluation of the BIGPIC model we focused on addressing these two questions to provide a foundation for future evaluation as we continue our efforts to scale up patient centric, holistic models of care in developing world settings. This project was the culmination of my prior efforts in Kenya and is now the focus of my ongoing implementation efforts. (24)

Commentary linking the work done

Project 1 – Training of staff to support the healthcare system (publication 1)

Introduction:

With the well documented limitations in the size of the healthcare workforce in SSA, one of our first priorities was to develop a model for training that could maximize the utility of the currently available staff.

In our effort to develop the workforce needed to support and sustain our various healthcare delivery programs, our primary emphasis was on creating experiential education programs to train the staff needed to oversee and scale up many of our envisioned future activities.

This includes a first of its kind experiential training program for students from the University of Nairobi (publication 1) (25), a post graduate diploma program in Clinical Pharmacy (publication 6) (26), and a masters in Clinical Pharmacy (Publication 6). The students enrolled in these programs now form the core leadership for the many activities described in the subsequent sections.

At the inception of these experiential education programs, we wanted to assess the impact of our Kenyan pharmacy interns in making clinical interventions in a Kenyan tertiary referral hospital. Despite the well documented impact of clinical pharmacists in high-income countries (HIC), there is only limited data describing the potential role of SSA pharmacy trainees in promoting clinical services.(27) Instead of continuing to promote a simple increase in the numbers of healthcare providers, our efforts have focused on increasing the output and impact of the already available healthcare resources. In order to prove the potential impact of our efforts, we compared the performance of North American pharmacy interns and Kenyan pharmacy interns in terms of the number of interventions they made during inpatient rounds.

Methods:

This study was a retrospective, pilot study of documented consultations provided by all pharmacy interns and Kenyan pharmacists at MTRH from August 2008 to October 2008. The primary objective was to describe and

compare consultations provided by both North American Doctor of Pharmacy interns and Kenyan Bachelors of Pharmacy interns to identify differences between North American and Kenyan student activities and further advocate for expansion of clinical pharmacy services within Kenya. This question is of importance as the North American model for pharmacy education has shifted to the more clinically oriented Doctor of Pharmacy curriculum as opposed to the Bachelors of Pharmacy curriculum still used in Kenya. With only limited examples of clinically oriented pharmacy practice to expand the scope of pharmacy practice in Kenya to include more clinically oriented activities, we wanted to assess whether the current curriculum and resultant workforce would be able to document a similar level of impact in terms of the number of clinical interventions(12, 28).

Descriptive statistics were used to evaluate commonly accepted consultations for type of consultation and pharmacotherapeutic area of consultation. Additionally, mean and median values were used to describe consultations provided by each student. The number, type, and pharmacotherapeutic area of commonly provided consultations were measured for Kenyan and American students. The intervention data were adjusted to 100 days of participation in patient care rounds. Parametric data were compared using the *t* test and nonparametric data were compared using the Wilcoxon rank-sum test.

Results:

During the period of evaluation, we found that the North American students documented 12.0 consultations per day compared with 16.7 consultations per day documented by Kenyan interns($p<0.001$). The most common areas of consultation were medication reconciliation, chart review, medication acquisition, and drug information for physicians (Table 1). Kenyan students provided significantly more consultations in the areas of drug information for families, patients, and nurses, medication acquisition from the pharmacy, and in clarification of medication orders ($p<0.05$) as seen in the table 1 and 2. North American students provided more consultations in the area of diagnostic laboratory tests ($p<0.001$).

Type of Consultation	PUCOP, No. (%)	PUCOP Per 100 Student-Days	UNSOP, No. (%)	UNSOP Per 100 Student-Days	Total, No. (%)	p^a
Blood pressure or fasting blood sugar monitoring	22 (1.4)	16	62 (1.3)	21	84 (1.3)	0.19
Dose calculation	30 (1.9)	22	45 (1)	15	75 (1.2)	0.69
Drug information for family	6 (0.4)	4	46 (0.9)	16	52 (0.8)	0.01
Drug information for patient	15 (0.9)	11	122 (2.5)	42	137 (2.1)	0.01
Drug information for nurse	32 (2)	24	180 (3.7)	62	212 (3.3)	0.01
Drug information for physician	108 (6.7)	81	227 (4.7)	78	335 (5.2)	0.13
Allergy prevented	3 (0.2)	2	12 (0.3)	4	15 (0.2)	0.54
In-service	7 (0.4)	5	17 (0.3)	6	24 (0.4)	0.80
Nutrition consult	9 (0.6)	7	19 (0.4)	7	28 (0.4)	0.95
Medication history	39 (2.4)	29	37 (0.8)	13	76 (1.2)	0.52
Medication reconciliation	5 (0.3)	4	21 (0.4)	7	26 (0.4)	0.20
Medication administration record reconciliation	601 (37.5)	449	2667 (54.7)	913	3268 (50.4)	0.09
Diagnostic laboratory test	91 (5.7)	68	78 (1.6)	27	169 (2.6)	0.01
Drug acquisition	49 (3.1)	37	314 (6.4)	108	363 (5.6)	0.01
Appropriate therapy	106 (6.6)	79	176 (3.6)	60	282 (4.4)	0.30
Chart review	374 (23.3)	279	552 (11.3)	189	926 (14.3)	0.15
Clarify/illegible order	25 (1.6)	19	108 (2.2)	37	133 (2.1)	0.02
Contraindication	5 (0.3)	4	15 (0.3)	5	20 (0.3)	0.85
Dosing issue	45 (2.8)	34	107 (2.2)	37	152 (2.3)	0.95
Drug interaction	9 (0.6)	7	15 (0.3)	5	24 (0.4)	0.34
Duplicate therapy	7 (0.4)	5	10 (0.2)	3	17 (0.3)	0.32
IV to PO conversion	15 (0.9)	11	40 (0.8)	14	55 (0.8)	0.99
Nonformulary request	1 (0.1)	1	6 (0.1)	2	7 (0.1)	0.44
Total	1604	1197	4876	1667	6480	0.01[b]

Abbreviations: APPE = advanced pharmacy practice experience, PUCOP = Purdue University College of Pharmacy, UNSOP = University of Nairobi School of Pharmacy, IV = intravenous, PO = per oral.

[a] Wilcoxon rank-sum test performed to compare interventions adjusted by the number of days

[b] A *t* test was performed to compare total interventions adjusted by the number of days

Table 1 – Type of Consultations Provided by American and Kenyan Pharmacy Students during an Acute Care APPE in Kenya

Therapeutic Category	PUCOP No. (%)	PUCOP Consultations Per 100 Student-days	UNSOP, No. (%)	UNSOP Consultations Per 100 Student-Days	Total (%)	p^a
Antibiotics	13 (11.1)	10	75 (14.2)	26	88 (13.6)	0.01
Anticoagulation	7 (6.0)	5	36 (6.8)	12	43 (6.7)	0.10
Cardiovascular	27 (23.1)	20	62 (11.7)	21	89 (13.8)	0.39
Endocrine	10 (8.6)	7	42 (8.0)	14	52 (8.1)	0.08
Gastrointestinal	8 (6.8)	6	40 (7.6)	14	48 (7.4)	0.05
HIV	20 (17.1)	15	107 (20.3)	37	127 (19.7)	0.01
Intoxications	0 (0)	0	6 (1.1)	2	6 (0.9)	0.10
Neurology	12 (10.3)	9	49 (9.3)	17	61 (9.5)	0.04
Oncology	2 (1.7)	1	12 (2.3)	4	14 (2.2)	0.22
Parasites/malaria	3 (2.6)	2	37 (7.0)	13	40 (6.2)	0.01
Respiratory	7 (6.0)	5	20 (3.8)	7	27 (4.2)	0.89
Tuberculosis	8 (6.8)	6	31 (5.9)	11	39 (6.0)	0.18
Vitamins	0 (0)	0	11 (2.1)	4	11 (1.7)	0.02
Total	117	87	528	182	645	0.02

Abbreviations: advanced pharmacy practice experience (APPE), Purdue University College of Pharmacy (PUCOP), University of Nairobi School of Pharmacy (UNSOP), Intravenous (IV), Per oral (PO)

[a] Wilcoxon rank-sum test performed to compare interventions adjusted by the number of days

Table 2 – Therapeutic Category of Consultations Provided by American and Kenyan Pharmacy Students in an Acute Care APPE in Kenya

Summary and significance of the publication

This study helped demonstrate several key findings that have helped support many of our future efforts in pharmacy education in Kenya. The results highlight the potential for a more clinically focused practice for Kenyan pharmacists with the current Bachelors in Pharmacy training. Furthermore, our results highlight the exemplary capability of Kenyan students as they documented significantly more interventions than their counterparts from North America. This study showed that the Kenyan students consistently provided more interventions in the aspects of healthcare delivery that require interdisciplinary collaboration and communicating with members of the community largely owed to their greater awareness of the local infrastructure and cultural norms. The North American interns showed a statistically significant increase in the number of interventions related to recommending laboratory tests which could be explained by the greater reliance on laboratory tests in North American settings as opposed to the greater reliance on clinical diagnosis in sub-Saharan Africa(29). The findings from this study emphasize the importance of contextualizing approaches around the local environment by working with local providers to guide all activities. While this study was limited by the small numbers of students included within both arms and relatively short period of assessment, it provided the initial pilot data to help justify the growth of our program in numerous domains related to pharmacy education.

Project 2 – Chronic Disease screening/linkage strategies (Publication 2)

Introduction:

As we continued to make considerable headway in creating effective training programs, we wanted to expand the reach of these highly trained individuals by having them address the major healthcare gaps plaguing rapidly developing countries like Kenya. Despite the recent increase in concern over the growing burden of hypertension and diabetes mellitus, there are very few studies reporting the prevalence of these diseases or replicable screening strategies in Kenya, especially in rural areas(30, 31). By 2025, the number

of adults with hypertension is predicted to increase by approximately 60% and almost three-quarters of the world's hypertensive population will be in low and middle income countries (32). Studies have also found similar trends in the prevalence of diabetes, with prevalence rates ranging from < 1% in rural areas to > 20% urban settings with variation according to racial/ethnic group (33). In order to begin tackling these growing problems, we wanted to focus our early efforts on better understanding the burden of disease while simultaneously studying the impact of two frequently utilized screening strategies on the health behaviors of patients. Therefore, we conducted a feasibility study to compare two strategies for screening in our catchment area: community-based versus home-based screening(34-36). Our primary aim was to provide an estimate of disease prevalence via both methods which could then be used to inform local public health policy and health system planning. We also assessed the likelihood of returning for care at a facility after being identified as screen positive via the two screening strategies.

Methods:

Within this pilot investigation, we sought to identify the prevalence of diabetes and hypertension by utilizing the two commonly utilized screening strategies in similar settings. Within the community-based screening arm, we organized village based health fairs to provide education and point of care glucose and blood pressure testing to all interested members of the community. Within the home-based screening arm, we utilized AMPATH's network of counselors to go door to door to screen people using the same point of care testing done in the community screening arm. All patients who screened positive were instructed to return to the facility for confirmation. All participants with complete data recorded in the screening register were included within this analysis. Descriptive analyses were used to characterize the demographic characteristics of the findings of the two different screening strategies. In both analyses, the percentage of participants with an initial positive screening was calculated. The Fischer's Exact Test was utilized to

compare the difference in the likelihood of screening positive for diabetes or hypertension in the home-based versus community-based screening strategy. Additionally, the likelihood of following up after a positive screening test was compared between the two screening strategies and odds ratios (OR) for a positive screening were calculated. Linear regression was performed to determine the characteristics associated with a positive screening for both diabetes and hypertension. All analyses were completed using STATA® (College Station, Texas, Version 8).

Results:

There were 236 participants in the home-based screening versus 346 participants in the community-based screening who met the inclusion criteria for this analysis with participants having a mean age of 37 (SD=15) and 39 (SD=13) years, respectively. The home-based screening strategy identified 13 participants (6% of the total population screened) with a SBP greater than or equal to 160mmHg compared to the community-based strategy which identified 35 participants (10% of the total population screened) as seen in Figure 4. Participants in the community-based screening were almost twice as likely to have a positive screening for hypertension compared to the home-based screening arm, however, this result was not statistically significant (OR=1.93, Fischer's exact test, P=0.06). With regards to diabetes screening, 54 participants (23%) and 27 participants (8%) in the home-based screening and community-based screening, respectively, met the predefined threshold requiring confirmatory blood sugar testing. Participants in the home-based screening were statistically significantly more likely to have a positive screening result than the participants in the community-based screening (OR=3.51, Fischer's exact test, P<0.01).

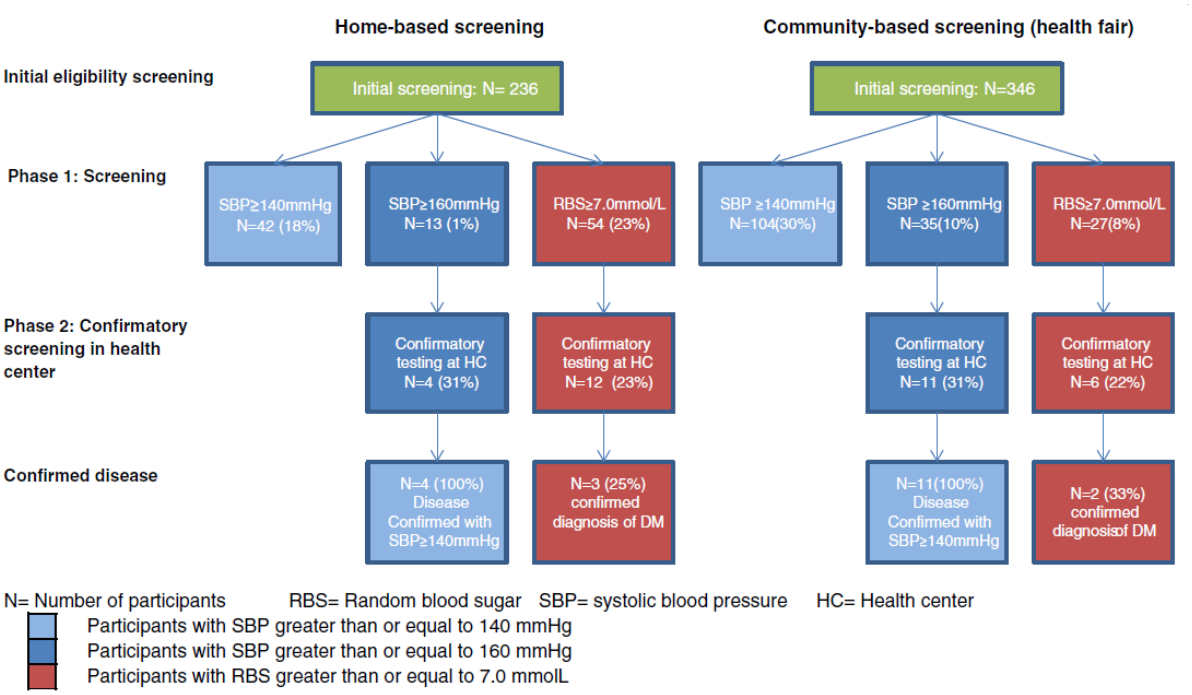


Figure 4 - Flow Chart for Screening Results in Home- and Community-based Screening

Follow-up rates

The primary finding of interest was the surprisingly low rate of follow-up for confirmatory testing in clinic for both screening strategies. Of the 13 participants (6%) in the home-based screening arm with a SBP ≥160mmHg, 4 (31%) returned for confirmation as seen in Figure 4. All 4 of these participants had a SBP ≥ 140mmHg when confirmatory testing was done. Similarly, in the community-based screening, 11(31%) of the 35 participants identified with an SBP ≥ 160mmHg returned for confirmation and all of these participants were confirmed to have a SBP ≥ 140mmHg. There were only negligible differences in the odds of returning for confirmatory follow up between the two groups (OR=0.97, Fischer's exact test, *P*=1.00)

In the analysis of blood sugar screening, 12(23%) of the 54 participants meeting the predefined criteria for referral returned for the confirmatory fasting blood sugar in the home-based screening with 3 receiving a confirmed diagnosis of diabetes mellitus. In the community-based arm, 6(22%) of the 27 participants returned for the confirmatory fasting blood sugar with only 2 participants being confirmatively diagnosed with diabetes.

There were only negligible differences in the odds of returning for confirmatory follow up between the two groups (OR=1, Fischer's exact test, *P*=1.00)
None of the participants in the home-based screening that had elevated blood pressures or blood sugars tested positive for HIV.

Summary and significance of the publication:
Prior to the completion of this study, we assumed that a more convenient and individualized home-based screening approach would lead to considerably higher rates of subsequent follow-up by patients at stationary facilities. While much of the research supporting these assumptions came from the focused investigation on HIV in SSA settings (37-42), we were surprised to find that the screening modality had no impact on the follow-up rates for NCDs. Furthermore, we were surprised by the unexpectedly low follow-up rates in all the subgroups as we did not anticipate such low rates of linkage to the public sector facilities in that region as they have a reputation for providing high quality services relative to other government facilities in Kenya(43). The findings from this study heavily influenced our future efforts as it highlighted the aversion rural patients show to seeking care at stationary facilities.

Project 3 Supply Chain - Revolving Fund Pharmacy
Introduction:
As we continued to better understand the burden of NCDs in settings where the primary healthcare focus had primarily been on infectious diseases, the limitations in addressing the multitude of other disease states patients in this setting face became clearly apparent. One of the major gaping holes was within maintaining a responsive supply chain. While medications for traditionally donor supported infectious diseases like tuberculosis and HIV were typically always available, the lack of funding for NCDs has forced rural patients to rely on public sector supply chain systems. Unfortunately, the lack of funding has resulted in dismal availability throughout sub-Saharan

Africa as reports have found NCD medication availability of approximately 36%(17). As we continued to build systems for managing diabetes and hypertension, the suboptimal supply chain became the primary rate limiting step for all of our expansion plans. To combat this, we wanted to build a donor *seeded,* but *patient sustained* model that worked in conjunction with the Ministry of health (MOH) instead of in isolation. To meet this requirement of being donor seeded, we established the Revolving Fund Pharmacy (RFP) which was designed to sustainably improve the responsiveness of the MOH supply chain. The model operates under the guiding principles seen in Table 3.

Principle	Explanation	Implementation
Access, not profit	RFPs operate in an access-maximization model where patients should not be denied life-saving medications. Instead of a profit-maximization model, we promote an access maximization model	A waiver system has been established to identify patients who are genuinely unable to pay the subsidized price. The profits from paying patients is high enough to cater for fee waivers
Shared ownership	All relevant local and international stakeholders must be incorporated into the development.	AMPATH has developed the RFP model in direct partnership with the Kenyan Ministry of Health, local communities, and funding partners
Secondary source of medications	MOH pharmacy must remain the primary source of supplies and medications for patients to avoid absolving the Ministry of Health of their responsibility in providing medications to patients. This is a crucial element to maintaining a healthy partnership.	The RFP charges a price that is generally higher than the MOH to ensure patients will preferentially access MOH medications whenever available. The RFP also has the flexibility to expand the formulary beyond the MOH to adjust to patient needs. In order to properly forecast needs, the RFP performs an initial and follow-up needs assessment of MOH medication availability, staffing requirements, space, and security needs to continuously maintain high quality service delivery in each area where RFPs are established.
Sustainable	With the desire to maximize access over the long term, pharmacy operations must be designed to be sustainable to ensure patients have continued access to medications.	In addition to the price markup, we have streamlined our operations and try to engage the efforts of already employed government staff whenever possible to minimize costs. We also invest in contextualized awareness activities
Accountability	Since money is being collected with every transaction, all operations must be held to the highest standards to avoid wastage or fraud. Stock takes and detailed reporting are required to account for inventory and dispensing, cash transactions and totals, the number of fee waivers, and drug availability.	RFP's are audited on a weekly basis during the first 1–2 months of operation. As facilities demonstrate increased capacity and reliable functionality, in-person auditing is reduced to a monthly or bi-monthly basis with reports being provided to the management committee and all relevant stakeholders on a monthly or quarterly basis as desired.
Distinct operation	RFPs must have the ability to operate in a semi-independent manner to ensure they are able to remain flexible and responsive to patient needs without being restricted to the bureaucratic limitations often found in governmental healthcare systems	The operation of the RFP is distinct from the MOH pharmacy to ensure separation of stocks, records and cash. The RFP is located in a different area in the facility, has unique receipts, and its own bank account all under the management of a committee comprised of the different stakeholders.
Facilitated drug procurement	There are many inefficiencies and potential points of diversion within medication supply chains in LMIC settings. Developing internal supply chain capacity is crucial to meeting the constantly changing needs of RFPs.	The AMPATH pharmacy team facilitates drug procurement to ensure efficient drug resupply, quality medication and access to good prices. The drugs are stored centrally at the warehouse located at AMPATH and subsequently supplied to RFPs as needed, based on a standard ordering system that is consistent with the governmental procedures for commodity management.

AMPATH, Academic Model Providing Access to Healthcare; LMIC, low and middle-income countries; MOH, ministry of Health; RFP, revolving fund pharmacy.

Table 3 – Guiding Principles to Govern the Revolving Fund Pharmacy

Methods:

In order to effectively characterize the design of the RFP for other implementers in LMIC's and provide a description of the utilization patterns, we completed a service evaluation to describe the impact of this model on the availability and purchase of medications.

Between one to three months prior to the implementation of RFPs through this project, a cross sectional availability assessment of 75 essential medications that the Kenyan MOH is responsible for supplying to facilities was performed at potential implementation sites. This evaluation was performed to generate a rough estimation of the needs of the potential implementation site facilities and to project the quantities of different medications needed to provide comprehensive care beyond HIV. After the implementation of the RFP model, the RFP staff in each facility maintained a daily list tracking the availability of essential medications. Auditors would then check these lists and perform a direct stock take to validate the findings and confirm the availabilities of medications. The percentage availability was then calculated by dividing the number of medications available by the total number of medications that are supposed to be stocked at each facility.

Results:

During the period of evaluation, three pilot RFP sites were started with formal agreements established with the management of the overarching facilities. For the selected sites, the initial cross sectional availability prior to RFP implementation for the 75 essential medications was 40% in Mosoriot health centre while Turbo health centre was 36%. Moi Teaching Referral Hospital in Eldoret houses an outpatient HIV clinic that previously only stocked non-HIV medications when they were donated, so their availability was sporadic and typically less than 10% (44).

Within each of the RFPs, the number of patient encounters had rapidly grown over the period of assessment as seen in Figure 3. In the first quarter of operations, the lowest volume RFP had an average number of 89 patient

encounters each week. However, by the fourth quarter of evaluation, the RFPs each had an average of over 200 patient encounters per week. During one year of evaluation, the three sites had a combined total of 33,714 patient encounters. Since many patients typically receive a prescription for more than one drug, the number of medications supplied is far more than this total, with the same patients likely returning for refills. As of February 2014, the first 3 RFPs have had a total of 115,991 patient encounters, with an average of 21%, 25% and 39% of total sales being attributable to chronic disease medicines in the Mosoriot Health Centre, Turbo Health Centre and Eldoret HIV clinic RFPs respectively.

In February 2014, nearly three years after starting the first RFP, a cross sectional analysis revealed that Mosoriot Health Centre's availability was 90%, Turbo Health Centre's was 94%, and the Eldoret HIV clinic's was 91%. All three facilities have demonstrated sustainable operations after 1 year of implementation and have only had to provide a waiver for services for less than 2% of patients served.

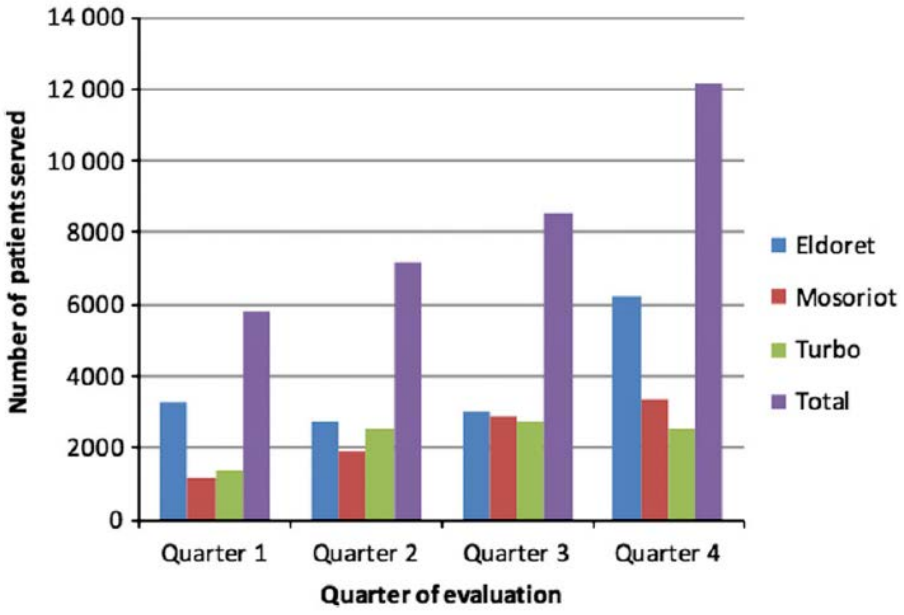


Figure 5 - Utilization Patterns for Three Sites of Evaluation

Summary and significance of the publication

The key finding from this paper was that the willingness to pay and demand for NCD medications was much higher than previously expected. Once

again, the literature surrounding HIV care has led us to assume that patients in these settings are unable to afford any user fees. Prior studies assessing HIV care found dramatic reductions in utilization of HIV services before and after the introduction of user fees(45). Within our RFP model, we were able to demonstrate consistent growth in utilization and had only 2% of the population receive waivers for medications due to an inability to pay. We were also able to demonstrate that many of the previously identified barriers within the MOH supply chain could be overcome by following a basic set of guiding principles designed to ensure sustainability, accountability, and affordability. The early demonstration of success with this model has now led to the expansion and creation of over 50 RFP's throughout western Kenya with plans underway to make our RFP model the primary model utilized by the MOH. All RFPs are still in operation and continue to enjoy an outpouring of support from the communities and facilities where they operate. This model has also facilitated the creation of an insurance product that includes access to the RFP as one of the primary benefits. In addition, the ability of the RFP to include non MOH supported medications within the formulary has also played a vital role in the expansion of many new care programs being introduced by AMPATH including services for maternal and child health, cardiovascular disease/venous thromboembolism, malignancies, and pediatrics.

Project 4 Remote Care Delivery (publication 4)

Introduction:

As we made improvements to medication access in public sector facilities and improved our understanding of patient behaviors with different screening strategies, we started to shift our focus to addressing the needs of patients requiring more intensive follow-up. Patients with insulin dependent diabetes serve as a prime example of this type of patient population as they require a basic level of facility based care combined with extensive self-care. The limitations in healthcare infrastructure in certain areas in SSA has created a

harrowing situation for most patients with insulin dependent diabetes as most are not expected to survive more than a year (46).

Despite practicing within one of Kenya's two tertiary referral centers, similar trends with poor care for patients requiring insulin were seen. The initial glycosylated hemoglobin (HbA1c) data from MTRH revealed that the average HbA1c was 10.4% (DCCT units) with patients requiring insulin being responsible for 63% of the HbA1c values above 14%(47).

This combination of realizations led us to establish a home-based self-monitored blood glucose (SMBG) program to provide intensive monitoring to patients with diabetes who were at high risk for complications. Our primary research question was to determine whether this care modality could lead to statistically significant reductions in blood glucose control after 6 months of enrollment.

Methods:

Within this program, patients were provided with counseling and a point of care glucometer to check their blood sugar twice a day from the comfort of their home and receive a weekly call where they would relay their results to specially trained providers and receive advice on dosage adjustments as outlined in a stepwise fashion in Figure 6.

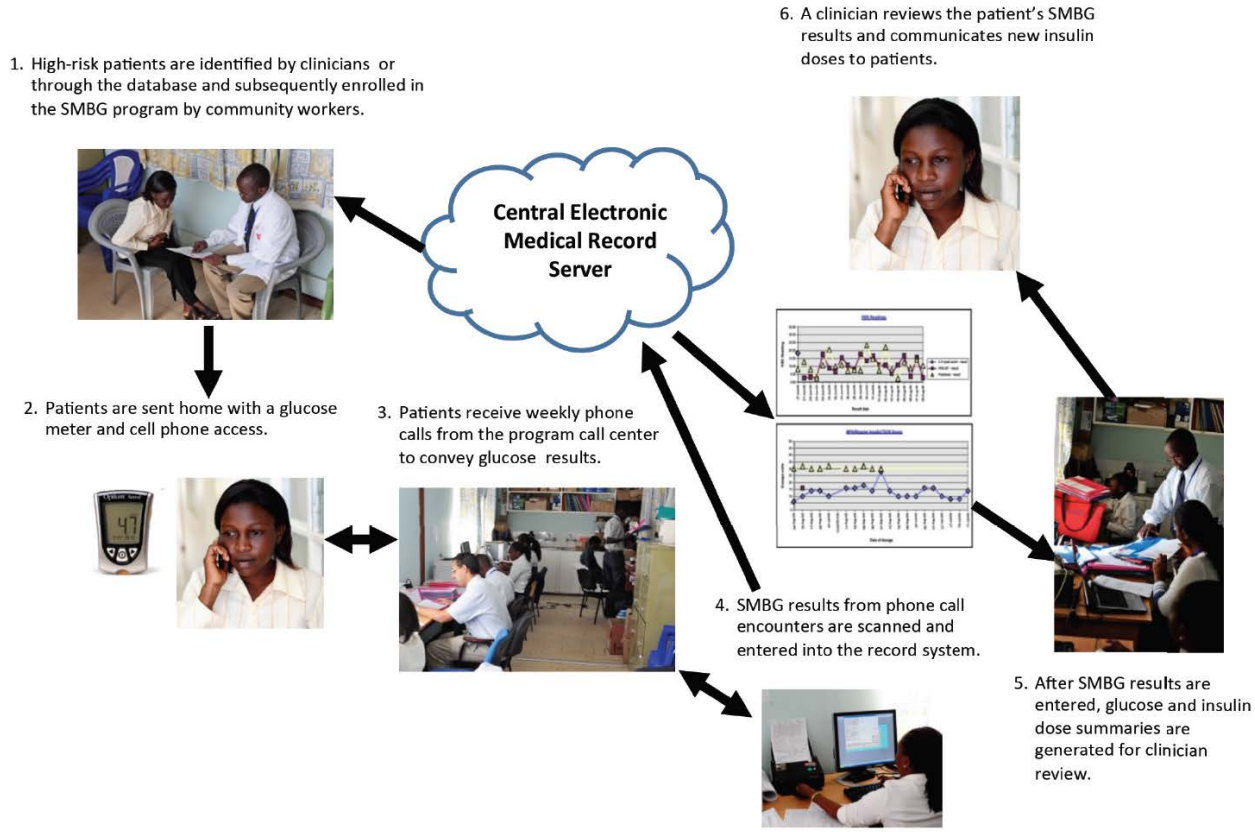


Figure 6 - Steps in Enrolling and Following up with Patients for the Self-Monitored Blood Glucose Program

During their routine in-person clinic visits, patients had A1C tests at 3- to 6-month intervals using the POC DCA Analyzer (Siemens, Erlangen, Germany). Whenever patients were registered to receive general diabetes care, diabetes staff and peer educators administered a comprehensive initial assessment form that captured a wide variety of demographic and personal characteristics.

The primary analysis was to demonstrate the impact of this approach in changing the median HbA1C from baseline to 6 months after enrollment. Because of the variability and unpredictability of patient follow-up visits, the date of the HbA1C was rounded up or down to the closest 3-month interval for the purpose of analysis. All patients included in this investigation had an evaluable result for the primary outcome measure. For all other HbA1C analyses, the HbA1C was recorded under the closest 3-month period from the date of enrollment. The Wilcoxon sign rank test was used to compare

baseline and 6-month HbA1C results and a *P* value <0.05 was considered statistically significant.

In addition to the primary outcome, the trends in SMBG changes from baseline were tracked and compared using the paired Student's *t* test. SMBG results from the first week, after testing supplies were received but before phone calls were initiated, were considered to be the baseline results. For patients who had prolonged enrollment beyond 6 months, SMBG results were analyzed descriptively to assess trends in results over an extended period of time and compared to the original baseline values to determine whether statistically significant differences in glucose control persisted. To identify potential trends in sub-populations within the program, univariate Wilcoxon rank sum analyses were performed to compare the change in A1C at 6 months against the demographic and personal characteristics collected during enrollment. Any characteristic showing a *P* value <0.2 was then introduced into an adjusted multivariate linear regression model to provide adjusted 95% confidence intervals for the percentage change in A1C from baseline to 6 months.

Results:

A total of 139 patients met the eligibility criteria and were included in the study. Two of these patients were later lost to follow up and excluded from the analysis because they did not have the required A1C test at 6 months. Analysis of the primary outcome across the full cohort (*n* = 137), found a statistically significant 4 point difference (*P*<0.01), between the median baseline (13.3%) and 6-month A1C results (9.3%) (31.6% absolute difference between the median baseline and 6-month A1C results). For patients who were followed beyond 6 months, a statistically significant decline (*P* <0.01) was maintained compared to baseline at each subsequent 3-month period of evaluation. Similarly, the SMBG program yielded statistically significant declines at each 3-month interval compared to baseline as seen in Figure 7.

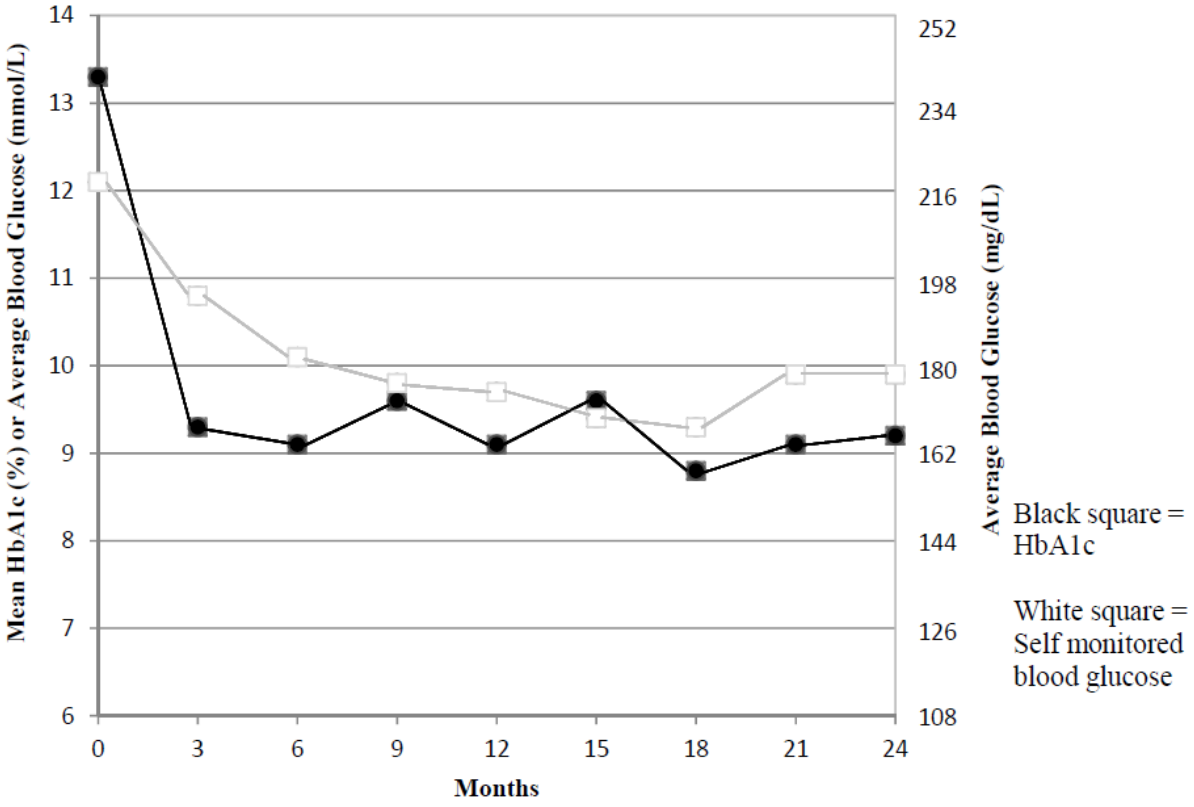


Figure 7 - Trends in Glycemic Control Amongst Self-Monitored Blood Glucose Participants

In the secondary analysis of factors that might be associated with response to this intervention, patients diagnosed with diabetes before the age of 25 years were statistically significantly more likely to have a lower percentage change in A1C after 6 months than the rest of the population, in both unadjusted and adjusted analyses (Table 4). A trend toward worse control among pediatric patients <15 years of age was also seen, but this was not statistically significant. Patients who were enrolled in the general diabetes care program for <5 years had a statistically significantly lower percentage improvement in A1C in both the adjusted (P <0.03) and unadjusted (P <0.001) analyses. Patients who received care in the rural clinic experienced a greater reduction in A1C than those who received care at the more urban MTRH clinic (P <0.01 in both adjusted and unadjusted analyses).

Characteristic	Population (*n* [%])	Change in Median A1C From Baseline to 4–8 months (%)	Interquartile Range Change in A1C (%)	*P* for Unadjusted Analysis	Adjusted Analysis 95% CI (%)	*P* for Adjusted Analysis
All patients	139 (100)	−31	−40 to −8			
Female patients	72 (51.8)	−14.5	−31 to 0	0.49		
Pediatric patients (<15 years of age)	8 (5.8)	−5.5	−12 to 1.5	0.05	−1.2 to 32.4	0.07
Diagnosed with type 1 diabetes by the age of 25 years	82 (60.0)	−9.5	−24 to 0	0.001	1.2–18.3	0.03
Enrolled in care for <5 years	79 (56.8)	−9.0	−26 to 0	0.003	0.5–16	0.04
Travel time to clinic >5 hours	36 (25.9)	−9.5	−26 to 2.5	0.15	−5 to 11.9	0.43
History of tuberculosis	7 (5.0)	−24.0	−30 to 7	0.64		
Caregiver assistance available	88 (63.3)	−13.5	−29.5 to 0	0.27		
Any alcohol consumption	9 (6.4)	−36	−43 to −11	0.1374	−21.4 to 11.4	0.54
History of smoking	4 (2.9)	−37	−37 to −18.5	0.21		
Any level of food insecurity	35 (25.2)	−20	−36 to −4	0.34		
Rural clinic (Webuye)	47 (33.8)	−31	−40 to −8	0.0004	−17.5 to −0.3	<0.01
Semi-urban clinic (Eldoret-MTRH)	92 (66.2)	−12	−24 to −1	0.0004	4.2–20.8	<0.01

Table 4 - Association of Risk Factors with Response to Self-Monitored Blood Glucose Intervention

Summary and significance of the publication

Patients in this setting receiving this previously unavailable care modality, showed a rapid and dramatic improvement in glycemic control. Prior to the implementation of this intervention, there was only one other published account of the impact of home glucose monitoring in SSA which came from South Africa(48). Our published account represents the largest published cohort describing the experience with home glucose monitoring and provided our team of investigators with considerable insight into the immense potential with self-care amongst populations which were thought to be incapable because of the low levels of literacy typically found in these settings (49). The capability of different types of patients with diabetes to benefit from this care modality was further supported by the statistically significant improvement in HbA1c amongst rural patients compared to the semi-urban population.

The findings from this study are consistent with the findings from one of the only other assessments of home blood glucose monitoring conducted in SSA in Soweto, South Africa which also showed a statistically significant decline in HbA1c(48). Despite the limited data available on this care modality in SSA, both studies have shown benefits similar to the well described benefits in high income countries where this care modality is a standard part of care.

Efforts should be undertaken to expand access to this service and further document the impact on care in much larger cohorts.

Project 5 – Integrated Care Delivery (Publication 5)

Introduction:

While all of the aforementioned projects reflect the implementation of contextualized stationary facility based healthcare delivery, they fail to address the large majority of patients who are unwilling to travel to receive care at public sector facilities. These prior models also only focused on the traditional aspects of healthcare instead of considering the broader determinants which heavily influence care seeking behavior especially amongst rural populations(15, 50). After years of studying all the aforementioned aspects of health care delivery in rural western Kenya described in this thesis, I designed the Bridging Income Generation through grouP Integrated Care (BIGPIC) model with my team of colleagues.

In western Kenya and throughout SSA, low linkage and retention to care contribute to the inadequate control of NCDs in rural settings (9, 12, 19, 20, 22, 51-53). In Kenya, over 50% of the population earns less than $1 per day, and user fees for rural outpatient NCD care have been shown to adversely affect access to care (54) (15). With 75% of the population living in rural areas and experiencing these economic realities in SSA, contextualized solutions for addressing the barriers to care for underserved rural populations must be found (6).

The BIGPIC model addresses these challenges by utilizing a stepwise care delivery model that is designed to address the unique barriers faced in rural settings. This model emphasizes the following steps: 1-Find patients portably, 2- Link to peer/microfinance groups, 3-Integrate education, 4-Treat portably, 5-Enhance economic sustainability, and 6 – Generate demand for care through incentives as seen in Figure 8 and explained within the methods section.

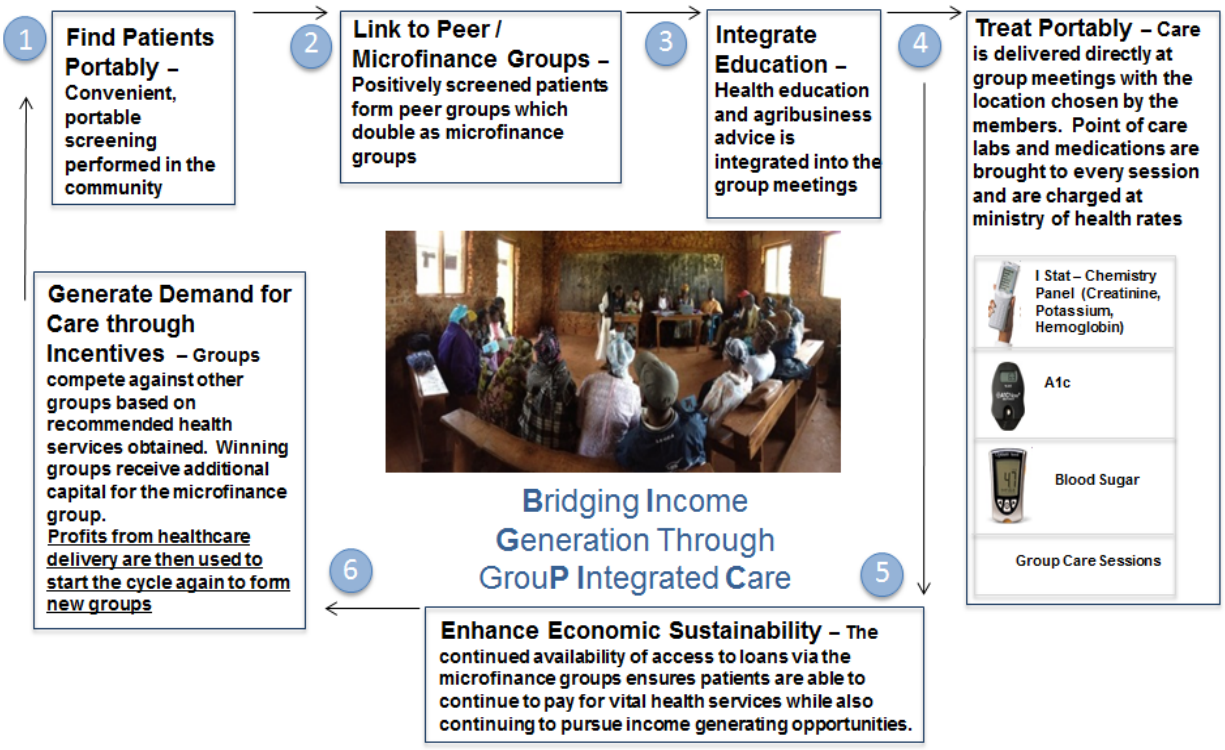


Figure 8 – BIGPIC Model of Care

Methods:

We implemented the pilot BIGPIC initiative in a rural area called Sinoko, which has an estimated population of 21,207 people, covers an area of 30.2 km, and is approximately 7 km from the nearest paved road. We screened individuals residing within a 3 km radius of a MOH supported dispensary(10, 55). Farming is the main economic activity for residents in this area.

The screening was conducted between November 2012 and April 2013 with different locations within Sinoko being targeted. Individuals who showed up for the screening were included within the data analysis for this evaluation. The only participants who were excluded from this study were those that refused to participate in any of the healthcare screening activities. All other participants were included within this evaluation.

Description of Intervention

BIGPIC utilizes an approach that is designed to combine six different pillars of service delivery into a single comprehensive system focused on sustainably delivering healthcare services as illustrated in Figure 8 and described below.

Pillar 1 - Find Patients Portably

Community health workers (CHW) received stipends from the program to make the community aware of the upcoming NCD screening and wealth generation activity that was planned through the implementation of the BIGPIC program by informing village elders and chiefs, distributing fliers, and making announcements at community gatherings. The BIGPIC activities were conducted through portable service delivery within the community and involved both microfinance experts and NCD trained staff. The NCD trained staff performed point of care screening using an automatic sphygmomanometer cuff to screen for hypertension and a portable point of care blood glucose meter to screen for diabetes. Patients who were confirmed to be screen positive were informed by local CHWs of the need for future follow-up that could be received by attending group meetings.

Pillar 2 - Link to Peer / Microfinance Groups

The CHWs informed all the positively screened patients of the date, time and location of the initial education session where all the detailed aspects of the intervention were explained with a special emphasis on microfinance. CHWs would communicate information to these individuals primarily by meeting them at routinely held local meetings or by visiting their houses as they typically reside within the community they serve. Participants were also contacted by phone if these other methods were not adequate. All participants then received guidance on forming self-selected peer microfinance groups of 10-30 members which included patients who were confirmed to have hypertension and/or diabetes along with members of the community who wanted access to microfinance services. The members of the microfinance group would decide on a meeting point for these microfinance meetings amongst themselves. Typical meeting points included houses of members, churches, and schools.

Pillar 3 - Integrate Education

In addition to receiving training on establishing microfinance groups, participants received health education on appropriate management of their

condition, ways to improve agricultural output, and the importance of saving money to prepare for future life events.

Pillar 4 - Treat Portably

After receiving basic health education including information on the ministry of health standard charges to be expected for portable health care services, the groups were visited on a monthly basis by trained healthcare providers during their microfinance meetings. These providers brought point of care laboratory tests, medications and provided consultations to all patients wanting to access care. Examples of charges patients paid for services include ~$1.00 USD for consultation with a clinician, ~$1.00 USD per point of care glucose test, and ~$0.01 USD per hydrochlorothiazide 50mg tablet.

Pillar 5 - Enhance Economic Sustainability

The economic component of the project was focused on establishing Village Savings and Loan Associations (VSLA) microfinance associations that were designed to assist communities with mobilizing and managing their own savings, providing interest-bearing loans to members without a requirement for collateral. While the core members of the group were all patients with hypertension and/or diabetes, additional members, regardless of health status, were allowed to join the groups up to a maximum of 30 members per group. Through the VSLAs, patients were able to access affordable loans and get business advice from program officers who were also responsible for ensuring groups accurately monitored and reported all financial transactions. At the end of each year, all members received a proportionate share of the savings and interest accumulated over the course of the year with their proportion being determined by their relative contribution to savings. The savings and interest generated from this activity were described descriptively.

Pillar 6 - Generate Demand for Care through Incentives

During the initial education sessions, the groups received instructions on the incentives that could be earned through the management of their health condition. Incentives were awarded at two levels of participation – the group level whereby the top three groups with the most improved process and

outcome metrics received rewards in the form of additional capital for the microfinance group, and at the individual level whereby each participant attaining pre-set goals received a reward, regardless of whether their group won or not. Within these scoring criteria, each patient was evaluated on their performance on basic process metrics including attendance at regularly scheduled clinic visits, purchase of medication refills, and payment for a recommended lab or radiological test. Clinical outcomes were also evaluated, however, these received much lower weighting in the overall score than the aforementioned process metrics. Any individuals scoring higher than 80% in this scoring criterion received a cash prize of ~$5; those meeting 100% receiving ~$10 and a cell phone valued at ~$15. For the group prizes, the group coming in first place received ~$10 per group member, second place received ~$7.50 per group member, and third place received ~$5 per group member. These incentive payments were paid from the revenue generated from care delivery and then paid out to members during the microfinance activities. The remaining revenue generated from payments for care was used to screen new patients and initiate the model in additional sites.

Analysis

The progression of participants through the five different phases of BIGPIC are illustrated in Figure 9: Phase 1-Initial Screening, Phase 2-Confirmation of Disease by Repeat Testing on the Same Day, Phase 3-Linked to Care by Attending Initial Care Education Session, Phase 4-Patients Joining Groups, and Phase 5-Patients Remaining in Care after 9 Months of Group Care.

Descriptive statistics were used to describe the primary outcome of linkage frequencies amongst patients who screened positive for either diabetes or hypertension. A positive linkage event was defined as having an individual who screened positive for hypertension and/or diabetes and then returned to a subsequent group meeting. An overall linkage frequency to return for care was calculated by dividing the number of screen positive individuals with a positive linkage event by the total number of screen positive individuals. In

addition, the linkage frequency amongst four different possible categories: hypertension only, diabetes and hypertension, diabetes only, or previously known history of diabetes and/or hypertension on treatment was also calculated. The linkage frequency of men versus women was also calculated using the chi-square test. In order to compare linkage frequencies with the BIGPIC approach relative to the more traditional model of healthcare delivery, the Fischer's exact test was utilized to compare the likelihood of linking to care in the current strategy compared to the previously published historical comparison group(51). In the historical group, a similar community-based screening strategy was utilized to identify individuals with hypertension and/or diabetes within an area that is located in the same county approximately 10 km away from the location studied within this pilot study. In the historical control, all screen positive patients were instructed to return to a stationary ministry of health facility for confirmation and subsequent care as opposed to the community-based model utilized within the current pilot. In both models, patients were informed of pre-specified days where confirmation testing would be available for free in the 1-month period following the screening. The same definition for a linkage event was used in both studies. In addition to the Fischer's exact test, a regression analysis controlling for known potential confounders such as age and gender was also performed.

For the secondary measure assessing clinical outcomes related to blood pressure, the paired t test was used to compare the baseline SBP and DBP results with the results obtained after 12 months from the initial screening activity. The mean blood pressure results were also calculated at 3 month intervals and compared to the baseline result. In addition to this clinical outcome, the percentage of patients retained within care was calculated by assessing the number of patients who remained in care (Phase 5) after joining the group care model (Phase 3). For diabetes-related measurements, descriptive statistics were used as there was an insufficient sample size to perform meaningful statistical analysis.

All statistical analyses were performed using Stata Statistical Software package® (StataCorp, College Station, TX) and a p-value <0.05 was deemed to be statistically significant.

Results:

A total of 879 individuals agreed to screening for chronic diseases with the majority (63.6%) of individuals being female.

To better understand the progression of patients through this model, Figure 9 provides an illustration of the flow of participants as they transitioned through the different phases.

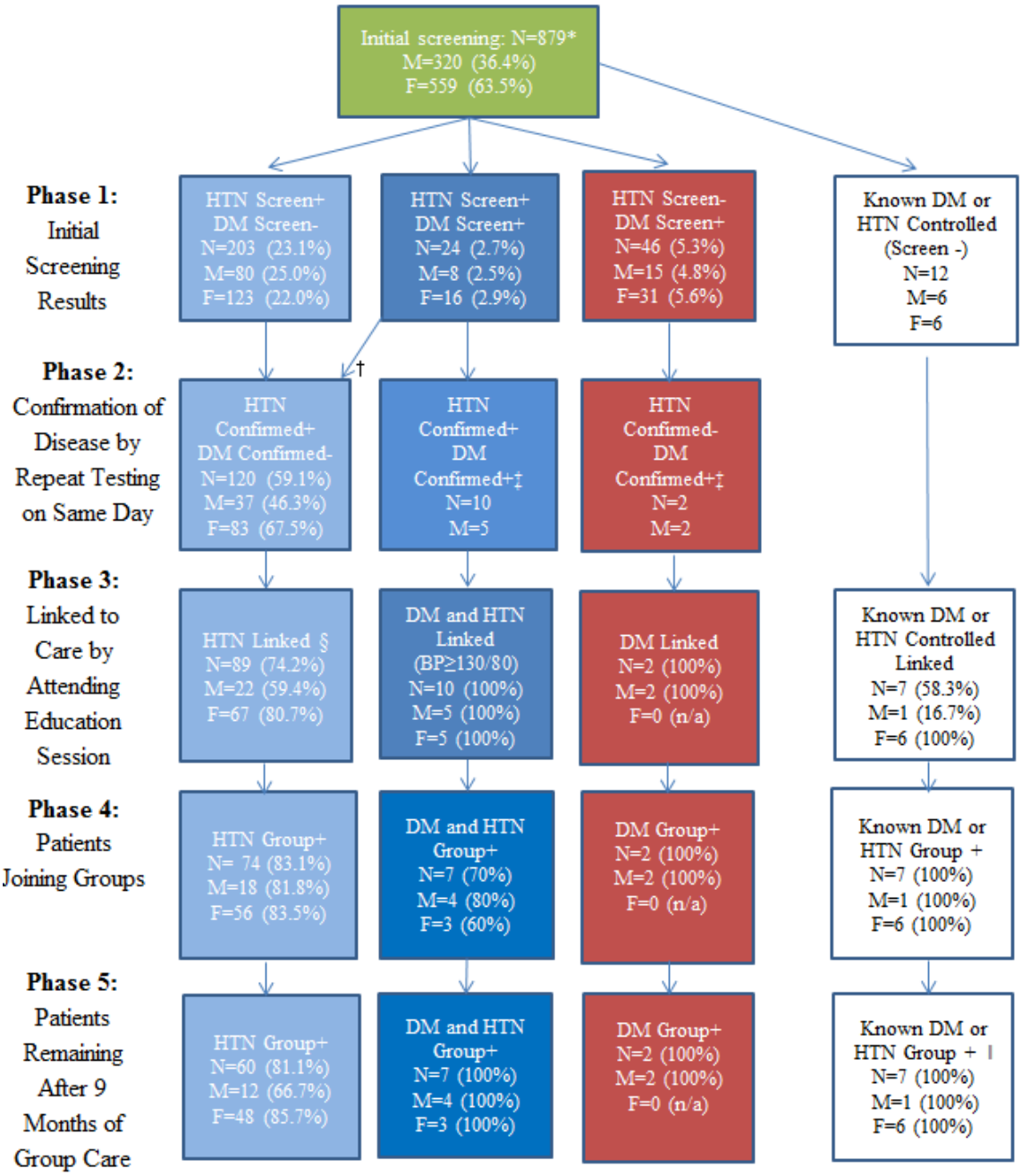


Figure 9 – Flow Chart of Participant Progression through the Linkage and Retention Cascade

M=male participants, F=female participants, RBS=random blood sugar, HTN=Hypertension, DM=diabetes mellitus, HTN Screen+ defined as SBP≥150mmHg or DBP≥90mmHg, DM Screen+ defined RBS≥7mmol/L (126 mg/dL)
*15 individuals refused blood sugar screening
†8 patients were HTN screen + and DM screen – on confirmation
‡32 patients were screened for DM via point of care HbA1c testing when available with 9 becoming positive
§ 8 patients didn't have an elevated blood pressure upon returning to the groups and were excluded from further care assessments
‖ 7 new female patients with known disease joined the groups over the course of the intervention

The initial screening results from Phase 1 found 23.1% were screen-positive for hypertension, 2.7% for diabetes and hypertension, and 5.3% for diabetes. Upon completion of repeat testing for hypertension in Phase 2, 120 (59.1%) screen-positive hypertension patients were confirmed with a second elevated blood pressure reading. In total, 125 patients (14.2%) were found to be hypertensive when including individuals who were known to already have hypertension. In the diabetes screen positive arms, the lack of availability of point of care HbA1c cartridges impeded the study from providing confirmatory diagnoses on the day of the screening for 38 patients. Despite being informed of the availability of free fasting blood sugar checks, only 2 patients returned for confirmation at a later date with only one of them being confirmed to have diabetes. Of the 32 participants who received confirmation on the day of screening via point of care HbA1c, nine patients were confirmed to have diabetes with four patients having markedly elevated HbA1c's above 13%. While a true estimation of diabetes prevalence is not possible with the limited follow-up, 1.4% of the population were confirmed to have diabetes with 10 patients having diabetes with hypertension and 2 patients with only diabetes.

In the primary linkage analysis in Phase 3, 72.4% of the patients with disease linked to the initial group care education session with linkage frequencies of 74.2%, 100%, 100%, and 58.3% for patients with hypertension, diabetes and hypertension, diabetes alone, and previously known disease, respectively. Women demonstrated a statistically significantly higher linkage frequency to care with 82.3% compared to 60.0% of men (OR=4.06, 95% CI [1.91-8.65], P<0.01) linking to the groups.

In the comparison of linkage frequencies with the historical control, there was a statistically significant, nearly three-fold higher likelihood of patients linking to care in the BIGPIC model compared to the traditional facility based care model (unadjusted OR=2.94, 95% CI [1.47 - 5.88], P<0.01 and adjusted OR=2.63, 95% CI [1.28 – 5.26], P<0.01).
In the analysis of the care cascade after attendance at this initial group care meeting (Phase 3), 90 out of 108 (83.3%) patients joined microfinance groups and began to receive monthly portable care (Phase 4). Of those 90 patients from Phase 4, 76 (84.4%) remained within the care model throughout the 9 months of group care (Phase 5). In analyzing the retention of the patients who initially linked to care (Phase 3) and then followed up with care over the remaining 9 months of the evaluation (Phase 5), we found 76 out of 108 participants (70.3%) remained in care throughout the intervention.

The analysis of the blood pressure data for the patients who were retained throughout the intervention revealed a statistically significant decline at 3 months from enrollment which persisted throughout the remaining period of evaluation for the intervention. After 12 months of enrollment (9 months of group care), patients demonstrated a statistically significant mean decline of 21mmHg in SBP (95% CI [13.9 to 28.4], P<0.01) and a statistically significant mean decline of 5mmHg drop in DBP (95% CI [1.4 to 7.6], P<0.01) as seen in Figure 10 and Table 5.

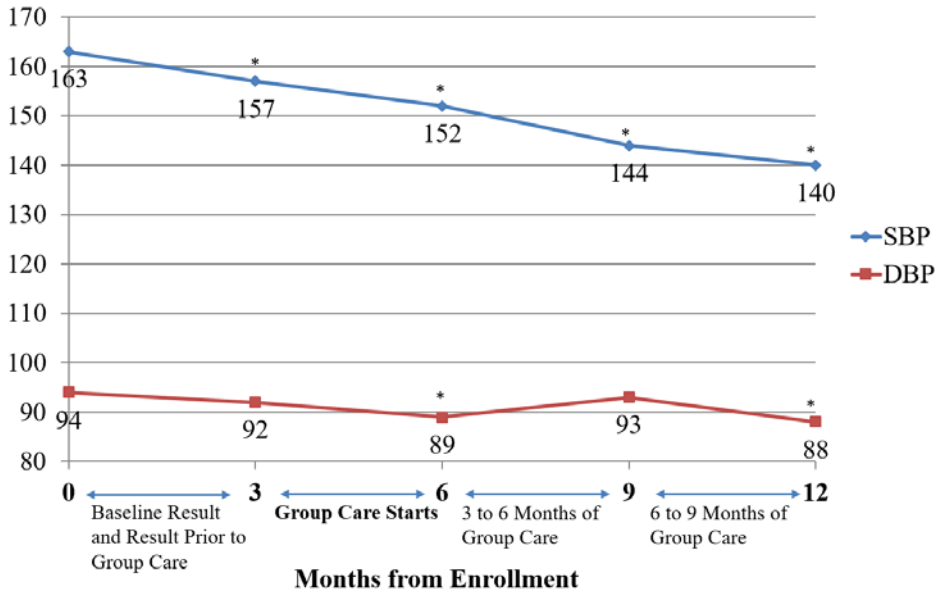


Figure 10 - Blood Pressure Trends Throughout the Care Cascade

*P<0.05 via two-sided paired t test compared to baseline screening result
SBP=systolic blood pressure in mmHg
DBP=diastolic blood pressure in mmHg

	Screening		**3 Month**		**6 Month**		**9 Month**		**12 Month**	
Number of available results at each interval -All -Women -Men	76 57 19		70 55 15		68 52 16		73 57 16		67 53 14	
	Mean SBP mmHg (95% CI)	**Mean DBP mmHg (95% CI)**	**Mean SBP mmHg (95% CI)**	**Mean DBP mmHg (95% CI)**	**Mean SBP mmHg (95% CI)**	**Mean DBP mmHg (95% CI)**	**Mean SBP mmHg (95% CI)**	**Mean DBP mmHg (95% CI)**	**Mean SBP mmHg (95% CI)**	**Mean DBP mmHg (95% CI)**
All	163 (158-169)	94 (91-97)	157 (152-162)	92 (89-95)	152 (147-157)	89 (87-91)	144 (139-149)	93 (90-95)	140 (135-145)	88 (85-91)
p-value*			0.04	0.25	<0.01	0.04	<0.01	0.64	<0.01	<0.01
Women	165 (160-171)	95 (92-98)	157 (151-163)	94 (90-97)	151 (146-157)	90 (87-92)	143 (138-148)	93 (90-96)	140 (135-145)	85 (85-92)
Men	157 (145-169)	90 (86-94)	157 (147-167)	86 (82-89)	152 (140-163)	87 (82-91)	146 (135-158)	91 (85-96)	139 (130-148)	84 (77-91)

Table 5 - Blood Pressure Trends throughout the Care Cascade Amongst People Attending the Initial Screening

*paired t test comparing screening result to results at different time intervals
SBP=systolic blood pressure
DBP=diastolic blood pressure

Over the course of the year, the microfinance activities of the groups resulted in a total accumulated savings of $6,616.85 with dividend interest payments totaling $3,120.40 (47.2%) which was all paid out at the end of the year amongst the 167 participants from the community with and without chronic disease.

A total of 32 patients were awarded for achieving individual targets with 4 patients achieving a score of 100% and 28 patients achieving a score between 80 and 100%. The top three groups were also awarded and received the financial payment during their microfinance activities.

Summary and significance of the publication

As LMICs continue to face an overwhelming burden of non-communicable diseases, integrated approaches like the BIGPIC model must be scaled up and investigated. By demonstrating a much higher linkage frequency and superior reductions in blood pressure than traditional care delivery models relying on stationary facilities, this initiative has the potential to offer promising strategies that may alter the current reality that patients with chronic diseases in LMICs face. The BIGPIC model represents a much needed departure from the donor dependent, facility-based models that are typically utilized with limited success in rural SSA settings. With the inclusion of long term, patient-driven financing strategies, the BIGPIC model of care represents a program that could potentially be adapted to rural settings found throughout LMICs. Efforts to broadly scale this model up are currently underway and there is a focused effort on determining which components of this model are responsible for the improvements in care. This study, however, had several limitations which limit the external validity of the findings. The study used a single arm study design which relied on convenience sampling within a health program (i.e. AMPATH) which has a department with extensive experience in providing microfinance and agricultural services. The use of convenience sampling also carries several limitations as it is possible this analysis included individuals who were more likely to seek out care and may not accurately represent the entire

community. However, to combat some of these limitations we are currently conducting a National Institutes of Health funded randomized controlled trial to evaluate the components of the model which are responsible for the pronounced improvement experienced by patients.

Other publications

Publications 6 & 7 Which approach to training should be used? (26, 56)

Most of the emphasis towards addressing the training needs in LMICs continues to focus primarily on increasing the quantity of providers available to deliver healthcare services with minimal consideration for the quality of trainees upon completion. Through the publication of our novel approaches to training, I have been invited to author two editorials/reviews on best approaches for training in LMICs. In publication 6, we describe how the current approaches to development need to be altered. The prevailing model for international development frequently includes boluses of reactive funding, external technical assistance, and often uncoordinated training efforts as brokered by aid organizations such as the Global Fund, the World Bank, and USAID(57). The effects of this treatment are rapid with benefits quickly disappearing upon removal of donor support. In contrast, an initial investment followed by smaller ever decreasing investments is much more likely to achieve long term benefits that create a responsive, proactive healthcare system rather than a reactive ineffective healthcare system that breaks in the face of every new crisis as seen with the recent Ebola epidemic in West Africa(56).

We have also published an invited review of the different levels of our pharmacy training program to describe our approach to developing the next generation of global health leaders from Kenya and North America(26). Through our activities we have trained over 300 North America and Kenya pharmacy students at different stages in their education. We have also expanded our program to incorporate training for medical students, medical residents, clinical officers, and peers to provide community-based support.

Publication 8 – What does Rural Diabetes Care look like?(58)

As the many stakeholders involved in building care infrastructure in SSA continue to try to address the burden of diabetes, the many differences between the presentation of diabetes in urban and rural areas must be considered before applying suboptimal solutions.

In order to highlight these unique differences, we published an invited article in Lancet Diabetes and Endocrinology to describe the characteristics of diabetes patients in rural Kenya. Our comprehensive efforts in Western Kenya have helped address the current lack of data from rural settings by assessing care from all angles. Our article highlighted the lower levels of health literacy, lower body weight / body mass index, long distances traveled to reach health facilities and the many costs patients have to pay when trying to access care in government facilities. In addition to describing barriers, our evaluation of this clinic also found that this rural diabetes populations had high levels of care taker support within the community to help them address their diabetes related care needs.

This paper has helped highlight the many unique characteristics that must be considered when delivering care to rural populations and has helped promote the need to treat patients with diabetes in rural SSA as a distinct condition with unique attributes requiring contextualized approaches(59).

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Factors in Hospitalized Patients" *Annals of Pharmacotherapy*. 2008:42; 491-497.
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Appendix 1 - Signatures of Contributing Authors

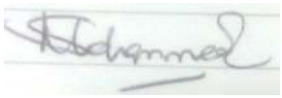
1. **Pastakia, S.D.**, Vincent W.R, Manji I., Kamau E., Schellhase E.M. *Clinical pharmacy consultations provided by American and Kenyan pharmacy students during an acute care advanced pharmacy practice experience.* Am J Pharm Educ, 2011. **75**(3): p. 42-45.

Imran Manji Ellen Schellhase


Unfortunately, I have not worked with Dr. Vincent since publishing this article over 5 years ago. He seems to have left his previous position and has changed his email address making it difficult to reach him. Dr. Kamau was a Kenyan student of mine who assisted with collecting data for this study but is no longer reachable by her previous email address or phone number.

2. **Pastakia, S.D.**, Ali S. M., Kamano J.H., Akwanalo C.O, Ndege S.K., Buckwalter V.L., Vedanthan R., Bloomfield G.S. *Screening for diabetes and hypertension in a rural low income setting in western Kenya utilizing home-based and community-based strategies.* Global Health, 2013. **9**: p. 21.

Shamim Ali Jemima Kamano Victor Buckwalter



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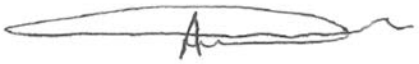
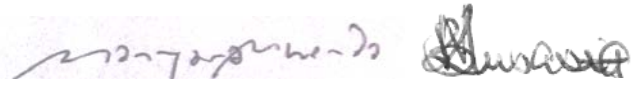


Dr. Ndege works primarily in the field and I have not been able to reach him for his signature. He had a very limited role on this publication.

3. Manji, I., Manyara S.M., Jakait B., Ogallo W., Hagedorn I.C., Lukas S.C., Kosgei E.J., **Pastakia S.D.** *The Revolving Fund Pharmacy Model: backing up the Ministry of Health supply chain in western Kenya.* Int J Pharm Pract, 2016. 24(5): p 358-366.

Imran Manji Simon Manyara Beatrice Jakait William Ogallo


Isabel Hagedorn Stephanie Lukas Eunice Kosgei



4. **Pastakia, S.D.**, Cheng S.Y., Kirui N.K., Kamano J.H. *Dynamics, Impact, and Feasibility of Self-Monitoring of Blood Glucose in the Rural, Resource-Constrained Setting of Western Kenya.* Clin Diabetes, 2015. **33**(3): p. 136-43.

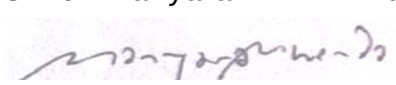
Stephanie Cheng Nicholas Kirui Jemima Kamano

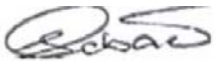


Pastakia S.D., Manyara S.M., Vedanthan R., Kamano J.H., Menya D., Andama B., Chesoli C., Laktabai J. Impact of Bridging Income Generation with GrouP Integrated Care (BIGPIC) on Hypertension and Diabetes in Rural Western Kenya. Journal of General Internal Medicine. 2016 Dec 5. [Epub ahead of print] PubMed PMID: 27921256.

5.

Simon Manyara Jemima Kamano Jeremiah Laktabai





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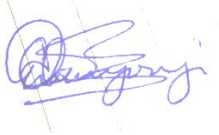
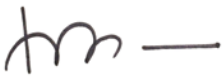
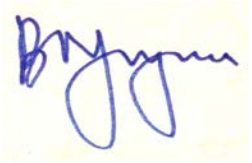



6. **Pastakia, S.D.**, Njuguna B., Le P.V., Singh M.K., Brock T.P. *To address emerging infections, we must invest in enduring systems: The kinetics and dynamics of health systems strengthening.* Clin Pharmacol Ther, 2015. **98**(4): p. 362-4.

Tina Brock Benson Njuguna

I worked only peripherally with Drs. Le and Singh as they are based in San Francisco, California, USA. I do not have their updated contact information and have had a challenge reaching them for their signatures.

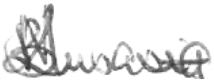
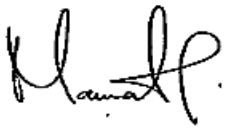
7. Miller, M.L., Karwa R., Schellhase E.M., **Pastakia S.D.**, Crowe S., Manji I., Jakait B., Maina M. *Meeting the Needs of Underserved Patients in Western Kenya by Creating the Next Generation of Global Health Pharmacists.* Am J Pharm Educ, 2016. **80**(2): p. 22-32.

Monica Miller Rakhi Karwa Ellen Schellhase



Susie Crowe Imran Manji Beatrice Jakait Mercy Maina



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Elizabeth O'Hara Nicholas Kirui Stephanie Cheng Patrick Chege




Victor Buckwalter Jeremiah Laktabai


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To: Chair of Graduate Studies, University of Warwick

From: Imran Manji, BPharm

Date: 14 Oct 2016

RE: Contribution statement for PhD by Publication for Sonak Pastakia

Contribution Statement

I (Imran Manji) served as the first and corresponding author for the following paper listed below.

1. Manji, I., **Pastakia S.D.**, et al., *The Revolving Fund Pharmacy Model: backing up the Ministry of Health supply chain in western Kenya.* Int J Pharm Pract, 2016.

Dr. Pastakia helped lead the publication of this paper and was one of the individuals responsible for conceptualizing the revolving fund pharmacy model and helped obtain the grant funds and local approvals to conduct this program. He also helped in reviewing the article and finalizing it for publication.

Sincerely,

Imran Manji, BPharm
Senior Pharmacist
Moi Teaching and Referral Hospital

PURDUE
UNIVERSITY

DEPARTMENT OF PHARMACY PRACTICE

Chair of Graduate Studies
University of Warwick

Contribution Statement

I (Rakhi Karwa) served as the corresponding author on the following paper cited below.

1. Miller, M.L., **Pastakia S.D.**, Karwa R (corresponding author) et al., *Meeting the Needs of Underserved Patients in Western Kenya by Creating the Next Generation of Global Health Pharmacists.* Am J Pharm Educ, 2016. **80**(2): p. 22.

Dr. Pastakia was one of the collaborators in the preparation of this paper and assisted with the design and leadership of the residency program described in this paper in addition to obtaining the grant funds and local approvals to conduct this program. He also helped in reviewing the article and finalizing it for publication.

Sincerely,

Rakhi Karwa, PharmD, BCPS
Clinical Assistant Professor
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rkarwa@purdue.edu

List of Abbreviations

LMIC	Low- and middle- income country
NCD	Non-communicable disease
BIGPIC	Bridging Income Generation through Group Integrated Care
SSA	Sub-Saharan Africa
DM	Diabetes mellitus
HTN	hypertension
AMPATH	Academic Model Providing Access to Healthcare
HbA1c	glycosylated hemoglobin
HIC	High-income country
PUCOP	Purdue University College of Pharmacy
UNSOP	University of Nairobi School of Pharmacy
APPE	Advanced pharmacy practice experience
IV	Intravenous
PO	Per oral
OR	Odds ratio
SD	Standard deviation
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
HC	Health center
RBS	Random blood sugar
FBS	Fasting blood sugar
MOH	Ministry of health
RFP	Revolving fund pharmacy
HIV	Human Immunodeficiency Virus
DCCT	Diabetes Control and Complications Trial
MTRH	Moi Teaching and Referral Hospital
EMR	Electronic Medical Record
POC	Point of care

SMBG	Self-monitored blood glucose
CHW	Community health worker
USD	United States dollars
VSLA	Village savings and loan associations
mmHg	Millimeters mercury
USAID	United States Agency for International Development